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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/786,937	01/22/97	BOUCHARD	P 205299/96001
			EXAMINER

18N2/1201
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1811
DATE MAILED: 12-01/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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DETAILED ACTION

Information Disclosure Statement

Applicant's Information Disclosure Statement received Aug. 4, 1997 has been considered. Please refer to Applicant's copy of the 1449 attached herewith. Please note that Applicant's 1449 is incomplete because the authors for references YR and ZR are not listed. Kindly resubmit a 1449 with the proper reference citation.

Specification

1. The disclosure is objected to because of the following informalities: there is no reference to a BRIEF DESCRIPTION OF THE DRAWINGS in Applicant's specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 3, 4, 6, 7, 8, 9, 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4, 6, 7, 10, the phrase "preferably" is improper because a broad range or limitation, i.e. LHRH antagonist, followed by a linking term, i.e. preferably, is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

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In claim 3, the phrase "substances other than exogenous gonadotropins" is vague and indefinite because it is not clear to the Examiner in view of the specification what other substances are encompassed by said "substances".

In claims 9 and 11, it is not clear to the Examiner what is meant by the limitation "rec. LH". There appears to be no reference in Applicant's specification to said limitation and how it is defined.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

5. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diedrich et al. In view of Felberbaum et al.

Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by administering a combination of exogenous gonadotrophins (HCG) and the LHRH antagonist Cetrorelix to

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said patients. Cetrorelix was administered at a dosage 3 mg daily starting on day 7 of the menstrual cycle. Diedrich also disclose that GnRH agonists given in combination with exogenous gonadotropins also results in more effective stimulation. Please see the abstract; page 789, **Results**, first full paragraph; page 790, second column, first full paragraph; page 791, first column, third paragraph.

Diedrich does not specifically teach treating infertility, yet the Examiner refers to Felberbaum et al. which teaches treating women with tubal infertility with a combination of exogenous gonadotropins (HMG) and Cetrorelix, wherein the Cetrorelix is administered subcutaneously at 3mg or 1 mg daily starting on day 7 of the menstrual cycle. Kindly refer to the abstract.

It would have been obvious to one of ordinary skill in the art to use the method taught by Diedrich to treat infertility because Felberbaum raises expectation of success by disclosing that ovarian stimulation is induced and further because Felberbaum, in addition to Diedrich, teaches that the disclosed treatment would be effective in the treatment Polycystic Ovary Disease. Furthermore, both Diedrich and Felberbaum disclose administration of the same gonadotropin/Cetrorelix combination to a patient using the same method steps and dosages set forth in Applicant's claims. Accordingly, treatment of fertility disorders would have been obvious.

With respect to using LH, LHRH or a LHRH agonist to inducing ovulation instead of HCG (taught by art), such a modification would have been obvious to one of ordinary skill in the art because it is known that the overall effect of LH and its agonists are to induce ovulation.

Finally, concerning claim 5, which recites administration of Cetrorelix in an amount in the range of 0.1 to 0.5 mg, optimization of dosage amounts is well within the capability of the skilled artisan.

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Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
Engel et al., 5,663,145.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

Nov. 24, 1997



DOUGLAS W. ROBINSON
SUPERVISORY PATENT EXAMINER
GROUP 1800